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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,244	10/26/2001	Walker R. Force	P 021286 0272501	9259

7590 01/26/2005

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,244	FORCE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *22-28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I (claims 1-21 and 29), drawn to CD40-specific antibodies and compositions thereof and the species of F5-77 for prosecution in the instant application, filed 9/13/04, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §. 818.03(a)).

Claims 1-21 and 29 are under consideration in the instant application.

Claims 22-28 and 30 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to nonelected inventions.

2. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-7, 14-15 and, 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the F1-102, F5-152, F2-103, F5-157, 72 or F4-465 as well as the G28-5 antibodies and associated hybridomas are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

5. Claims 4-7, 14-15 and, 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7, 14-15 and, 17-20 are indefinite in the recitation of "F1-102", "F5-152", "F2-103", "F5-157", "72" or "F4-465" as well as the "G28-5" antibodies because their characteristics are not known. The use of "F1-102", "F5-152", "F2-103", "F5-157", "72" or "F4-465" as well as the "G28-5" antibodies as the sole means of identifying the claimed antibodies renders the claims indefinite because these are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same laboratory designations to define completely distinct cell lines.

Amending the claims to recite the appropriate ATCC Accession Numbers would obviate this rejection.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-11 and 19-21 are rejected under 35 U.S.C. § 102(e) as being anticipated de Boer (U.S. Patent No. 5,874,082) (1449; #DR) (see entire document).

De Boer et al. teach both agonistic and antagonistic anti-CD40 antibodies (see entire document). De Boer disclose that all anti-CD40 known in the art have a stimulatory effect on B cells (column 2, paragraph 3) and teach antagonistic anti-CD40 antibodies (see Summary of the Invention, Detailed Description of the Invention and Claims). De Boer et al. teach that recombinant forms of antibodies and antibody fragments as well as pharmaceutical compositions thereof can be used for a variety of procedures (see Detailed Description, particularly columns 5-10). De Boer et al. teach a variety of assays to test anti-CD40 antibodies (e.g. B cell proliferation assay, B cell activation assay, immunoglobulin quantification) (see entire document) and that CD40 epitopes can be identified (see column 7, paragraph 4 - column 8, paragraph 2).

The products of the instant claims and the prior art are defined in terms of certain functional characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Given the properties of both agonistic and antagonistic anti-CD40 antibodies, including a number of binding and functional assays taught by de Boer, the claimed binding and functional properties of anti-CD40 antibodies would have inherent properties associated with said agonistic and antagonistic taught by the prior art.

8. Claims 1-11 and 19-21 are rejected under 35 U.S.C. § 102(e) as being anticipated Siegall (US 2004/0235074 A1) (see entire document).

Siegall et al. teach classes of both agonistic and antagonistic anti-CD40 antibodies (see entire document, including Section 2.2. Anti-CD40 Antibodies in the Background of the Invention; Summary of the Invention and Detailed Description of the Invention). In addition, Siegall et al. teach recombiant antibodies and fragments thereof (see Antibody Derivatives in Section 5.6, particularly paragraphs [0077] – [0091]) as well as Formulations (See Section 5.9.2, particularly paragraph [0122] – [0133]). In addition, Siegall et al. exemplify various assays to study the test anti-CD40 antibodies (see Examples).

The products of the instant claims and the prior art are defined in terms of certain functional characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Given the properties of both agonistic and antagonistic anti-CD40 antibodies, including a number of binding and functional assays taught by Siegall et al., the claimed binding and functional properties of anti-CD40 antibodies would have inherent properties associated with said agonistic and antagonistic taught by the prior art.

9. Claims 3-7 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ahuja et al. (U.S. Patent No. 6,482,411) ([redacted]) (see entire document).

Ahuja et al. teach both agonistic anti-CD40 antibodies, including recombinant antibodies and antibody fragments thereof as well as pharmaceutical compositions thereof (see entire document, including columns - 62). De Boer disclose that all anti-CD40 known in the art have a stimulatory effect on B cells (column 2, paragraph 3) and teach antagonistic anti-CD40 antibodies (see Summary of the Invention, Detailed Description of the Invention and Claims). Ahuja et al. teach that CD40 agonists activate CD40 and prevent apoptosis in a variety assays (see Description of Illustrative Embodiments, starting on column 9 and CD40 agonists starting on column 24).

The products of the instant claims and the prior art are defined in terms of certain functional characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Given the properties of both agonistic and antagonistic anti-CD40 antibodies, including a number of binding and functional assays taught by Ahuja et al., the claimed binding and functional properties of agonistic anti-CD40 antibodies would have inherent properties associated with said agonistic anti-CD40 antibodies taught by the prior art.

10. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-21 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, , 6, 8, , 23, 24, 26, , 65-88 of copending application USSN 09/844,684 Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or nearly the same anti-CD40 antibodies. Although the instant claims do not recite cell lines or hybridomas expressing said antibodies, such cell lines expressing antibodies were well known and practiced in the antibody art either in the producing of said antibodies (e.g. monoclonal antibody technology or recombinant antibody technology) at the time the invention was made. Although, the copending claims are drawn to human antibodies and the instant claims do not recite human antibodies per se, it was well practiced and known by the ordinary artisan to employ various antibody forms, including human antibodies in clinical practice. In addition to the interacting with human cell receptors and interactions, human antibodies had the well known advantage of being less immunogenic and of having an increased half-life in human patients.

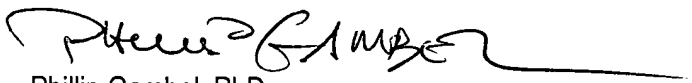
This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Due to high polymorphism of antibodies, the specific antibodies set forth in claims 12-21 and 29 are deemed structurally distinct on the primary amino acid basis and therefore free from the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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January 24, 2005